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# The effects of a comprehensive physiotherapy intervention for adults with joint hypermobility

**Submission date**
20/07/2012

**Recruitment status**
No longer recruiting

**Registration date**
23/07/2012

**Overall study status**
Completed

**Last Edited**
04/07/2016

**Condition category**
Musculoskeletal Diseases

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

## Plain English summary of protocol

Background and study aims
This study aims to develop and test a comprehensive physiotherapy treatment package for people with joint hypermobility (these people are often described as being double-jointed). People with hypermobility have problems with many daily activities, ranging from walking to picking up small things with their fingers. Physiotherapy (including exercise, advice and education) is the main treatment but we dont know how effective it is. This study will therefore involve the design and testing of a comprehensive physiotherapy treatment.

Who can participate?
The study will involve people over the age of 18 years who have been diagnosed with joint hypermobility syndrome and who have been referred for physiotherapy.

What does the study involve?
Early stages of the research will involve speaking with groups of patients and health care professionals about physiotherapy for joint hypermobility. The physiotherapy treatment and supporting information will be developed on the basis of these discussions. We will then train physiotherapists to deliver the treatment and it will be used with a small number of patients. We will ask patients and their physiotherapists about their experiences of the treatment and it will then be improved on the basis of that feedback. Finally, a small project will be carried out to see how easy it will be to do a much bigger study in the future. All patients will receive general advice about managing their condition in the form of booklets. These will be discussed with the physiotherapist and they will be given an opportunity to ask questions. Patients will then be randomly chosen so that half will only receive general advice and the other half will also receive the comprehensive physiotherapy treatment. Those chosen to receive physiotherapy will then have six treatments across a period of four months. All patients will complete some questionnaires at the start of the trial, at four months and again at seven months. The questionnaires will ask about their pain, beliefs about their condition, mobility, their ability to exercise, quality of life and their general health. We will also interview some patients to find out more about being part of the research, how acceptable the treatment was (should they have received this) and how acceptable the advice intervention was. The main things we want to find

out are how many people could possibly take part in the research, how many did take part, and other practical information about doing the trial. All of this information will tell us whether it is worth doing a much larger trial to confirm whether physiotherapy works or not.

What are the possible benefits and risks of participating?
All patients are likely to benefit from general advice. Those receiving the physiotherapy treatment have the potential to gain additional benefit, although evidence for the effectiveness of physiotherapy has not yet been established. Potential risks may be a temporary increase in pain during or following exercise. This is likely to be similar to the normal muscle ache that people often get the day following unaccustomed activity and is likely to resolve after a few days and will improve over time as they get used to being active. What is learned from all stages of the research may help the future treatment of people with joint hypermobility.

Where is the study run from?
The study is based at North Bristol NHS Trust and also involves the Royal National Hospital for Rheumatic Diseases in Bath and researchers from the University of the West of England, Bristol University and Bath University.

When is the study starting and how long is it expected to run for?
September 2012 to June 2015

Who is funding the study?
The National Institute for Health Research, Health Technology Assessment Programme (UK)

Who is the main contact?
Dr Shea Palmer
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# Contact information

### Type(s)
Scientific

### Contact name
Dr Shea Palmer

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# Additional identifiers

### EudraCT/CTIS number

### IRAS number

### ClinicalTrials.gov number

### Secondary identifying numbers
HTA 10/98/05

# Study information

### Scientific Title
N/A

### Study objectives
The study aims to:
1. Develop a comprehensive physiotherapy intervention for adults with joint hypermobility syndrome (JHS) informed by patient and clinician focus groups
2. Pilot implementation of the intervention in practice in two hospitals
3. Conduct a randomised controlled feasibility study of the intervention to determine:
3.1. The number of potential eligible patients with JHS
3.2. The feasibility of recruitment and retention
3.3. Acceptability of the research design and physiotherapy intervention to patients in terms of quality of life
3.4. Acceptability and feasibility of the physiotherapy intervention to physiotherapists in terms of training and implementation
3.5. An estimate of the value of information (VOI) from a subsequent RCT
4. Develop a final RCT protocol to determine the clinical and cost-effectiveness of the intervention

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
Not provided at time of registration

### Study design
Single-blind randomised controlled parallel-group feasibility study

### Primary study design
Interventional

### Secondary study design
Randomised controlled trial

### Study setting(s)
GP practice

### Study type(s)
Quality of life

### Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

## Health condition(s) or problem(s) studied
Joint Hypermobility Syndrome

## Interventions
Intervention:
A comprehensive physiotherapy intervention developed as part of the study (6 appointments across 4 months).

Comparator:
Condition-specific advice booklets, discussed with the physiotherapist (one-off intervention).

## Intervention Type
Other

## Phase
Not Applicable

## Primary outcome measure
Stage 1: To develop a comprehensive physiotherapy intervention for adults with JHS following focus groups with patients and clinicians.
Stage 2: To pilot implementation of the intervention in practice in two hospitals.
Stage 3: To determine:
1. The number of potential eligible patients with JHS
2. The feasibility of recruitment and retention
3. Acceptability of the research design and physiotherapy intervention to patients in terms of quality of life
4. Acceptability and feasibility of the physiotherapy intervention to physiotherapists in terms of training and implementation
5. An estimate of the value of information (VOI) from a subsequent RCT

## Secondary outcome measures
Stage 3: To pilot outcome measures planned for a definitive RCT. These include:
1. Physical function, pain, global status, fatigue, and self report joint count (Multidimensional Health Assessment Questionnaire)
2. Pain at rest and on movement (visual analogue scales)
3. A new condition-specific physical function questionnaire being developed by the research team
4. Health-related quality of life preference score (EQ-5D)
5. Exercise self-efficacy (exercise self-efficacy scale)
6. Illness perceptions (illness perception questionnaire)
7. Resource use questionnaires
8. Adverse events (e.g. dislocations or other injury)

## Overall study start date
01/09/2012

## Completion date
30/06/2015

# Eligibility

### Key inclusion criteria
1. More than 18 years old
2. Able to give informed consent
3. Able to understand and communicate in English
4. Fulfil the Brighton criteria for JHS (Grahame et al 2000)

### Participant type(s)
Patient

### Age group
Adult

### Lower age limit
18 Years

### Sex
Both

### Target number of participants
Stage 1: 32 patients, 32 clinicians; Stage 2: 10 patients; Stage 3: 60 patients

### Key exclusion criteria
1. Failure to meet the inclusion criteria
2. Other known musculoskeletal pathology causing pain, particularly osteoarthritis and inflammatory musculoskeletal disease such as rheumatoid arthritis
3. Other serious pathology including malignancy
4. Conditions affecting ability to exercise e.g. uncontrolled cardiovascular disease
5. Recent physiotherapy for JHS (within the last year)
6. Pre-existing psychological distress or psychiatric conditions.

### Date of first enrolment
01/09/2012

### Date of final enrolment
30/06/2015

# Locations

### Countries of recruitment
England

United Kingdom

### Study participating centre
**University of the West of England**
Bristol

United Kingdom
BS16 1DD

# Sponsor information

### Organisation
North Bristol NHS Trust (UK)

### Sponsor details
Research & Innovation Department
Learning & Research Building
Southmead Hospital
Bristol
England
United Kingdom
BS10 5NB
+44 (0)117 3236468
research@nbt.nhs.uk

### Sponsor type
Hospital/treatment centre

### Website
http://www.nbt.nhs.uk/

### ROR
https://ror.org/036x6gt55

# Funder(s)

### Funder type
Government

### Funder Name
Health Technology Assessment Programme

### Alternative Name(s)
NIHR Health Technology Assessment Programme, HTA

### Funding Body Type
Government organisation

### Funding Body Subtype
National government

**Location**
United Kingdom

# Results and Publications

**Publication and dissemination plan**
Not provided at time of registration

**Intention to publish date**

**Individual participant data (IPD) sharing plan**

**IPD sharing plan summary**
Not provided at time of registration

**Study outputs**

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Results article | results | 01/06/2016 | | Yes | No |